462586-00

Bayer CropScience

April 26, 2004

Document Processing Desk—6(a)(2)
Office of Pesticide Programs
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Subject: 6(a)(2) Report re:
Glufosinate-Ammonium Technical; EPA Reg. Number 264-646
Liberty® Herbicide; EPA Reg. Number 264-660
Liberty® ATZ Herbicide; EPA Reg. Number 264-668
Remove™ Herbicide; EPA Reg. Number 264-663
Rely® Herbicide; EPA Reg. Number 264-652
Finale® Herbicide; EPA Reg. Number 432-1229

Recent Data Generated in Response to Questions Raised by RMS Sweden: Anaerobic Soil Metabolism (Bayer Study No. M1261285-5)

We have recently learned that Bayer CropScience (Europe) submitted (February 2004) a non-guideline anaerobic soil metabolism study (Bayer Study No. M1261285-5, copies enclosed) to address questions raised by the European Union Rapporteur Member State – Sweden (RMS Sweden) concerning an existing guideline study (Bayer Study No. A41299: MRID 41323119). The new study was performed specifically in response to RMS Sweden for submission to the EU. According to RMS Sweden comments regarding the original guideline study, two metabolites were not declining at the end of the study and the parent degraded to such a low level during the seven-day aerobic portion that its behavior in the anaerobic phase was difficult to discern.

To address the questions raised by Sweden, Bayer CropScience conducted a study whereby the problem of aerobic degradation of glufosinate-ammonium was avoided by establishing an exaggerated artificial system that eliminated the aerobic portion normally included in a guideline anaerobic study. The estimated laboratory anaerobic DT_{50} from this non-guideline study is >125 days. The current anaerobic DT_{50} for glufosinate-ammonium based on U.S. EPA guideline studies is 56 days. A copy of the summary prepared by Sweden is attached (Attachment I).

The recent study conducted to address questions raised by Sweden was not conducted by current U.S. EPA guidelines (e.g., Anaerobic Soil Metabolism: OPP Guideline 162-2 and/or Anaerobic Aquatic Metabolism: OPP Guideline 162-3). The results of the new study do not alter the validity of the current estimated anaerobic soil half-life of 56 days and clearly address degradation kinetics under an artificial anaerobic scenario. The study, by design, is not a repeat of any required guideline study that has been submitted to the Agency in support of the

current glufosinate-ammonium registration. Bayer CropScience does not believe the data represent any new potentially adverse effect associated with the registered uses of glufosinate-ammonium.

This information is being submitted to the EPA pursuant to the Agency's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA.

Sincerely,

Valerie E. Wolford

Valerie E. Wolford
Documentation & Regulatory Services
Regulatory Affairs

/enclosures

Attachment I. Summary of Non-Guideline Anaerobic Soil Metabolism Study (Bayer CropScience Study Number M1261285-5) Prepared by RMS Sweden

B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

In the Draft Assessment report, a data gap was identified concerning anaerobic degradation in soil. A new study was submitted in February 2004. A summary and evaluation is given below. The results should be taken into account at Member State level.

B.8.1.2 Anaerobic degradation

Stupp, 2003

Methods

The metabolism of [3,4-14C]-radiolabelled glufosinate-ammonium was examined under anaerobic conditions in a sandy loam (pH 6.0, OC% 0.9) from Frankfurt-Hoechst, Germany (see table below) at a concentration of 1.96 mg/kg (equivalent to a field rate of about 1.5 kg active ingredient/ha). The radiochemical purity of the test substance determined by HPLC was 96 %. The experiment was conducted in compliance with GLP standards and in accordance with EC/SETAC/OECD guidelines.

The soil was pre-equilibrated before application under anaerobic conditions for 36 days. The test systems consisted of 100-g aliquots of soil in Erlenmeyer flasks equipped with traps for collection of CO2 and volatile organic compounds. To obtain anaerobic conditions, the soil was flooded with de-ionised water (about 1 - 2 cm water layer) and thoroughly flushed with nitrogen. After establishment of anaerobic conditions the test substance was applied to the water layer and the test systems were incubated under anaerobic conditions for 125 days at 20±1°C in the dark.

Table B.8.1.2.a: Characterisation of the sandy loam SLV soil used to investigate degradation and metabolism of GA under anaerobic conditions

Parameter	Results/Units
Texture Class (according to USDA)	Sandy loam
Sand (2,000 – 50 µm)*	56%
Silt (<50 - 2 µm)*	31%
Clay (<2 µm)*	12%
pH (in 10 mM $CaCl_2$)*	6.0
Organic Matter[1]*	1.6%
Organic Carbon*	0.9%
Soil Microbial Biomass [mg microbial C /kg dry wt]	Initial (before flooding, without a.s): 235 / 212 in the two duplicates
Quantity of of anaerobic bacteria at day 125 after application [colonies/mL]	183/248 colonies, dilution of extract (1 g soil and 10 mL solution) 10exp-4
Cation Exchange Capacity*	6.2 meq/100 g
WHC_{max}*	36 g water and 100 g soil (DM)
Field Moisture Capacity at 0.33 bar	20 g water and 100 g soil (DM)
Bulk Density (disturbed)	1.2 g/cm^3

1) % organic matter = % organic carbon x 1.724

**: Values are mean values from 46 batches, individual data are included in raw data.*

Samples were analysed at days 0, 1, 5, 7, 13, 29, 63, 95 and 125 after application. At each sampling interval two replicates were extracted with water and acetonitrile. The radiolabelled residues were analysed by HPLC using an ion exchange column and radiochemical detection. The identification of test substance and metabolites was confirmed by LC-MS/MS or by co-chromatography using labelled reference substances. A second HPLC method with different selectivity was used as confirmation method.

Results

The total radioactivity recovered throughout the study for individual samples ranged from 95% to 99% (mean 97%) of the applied radioactivity. Most of the applied radioactivity was water extractable (93% at day 0 to 69% at day 63) and a further part (1.5% at day 1 to 5.9 at day 95) was released by extraction with hot water and acetonitrile. Glufosinate-ammonium decreased slowly from an average of 89% of the applied radioactivity directly after treatment to 70% at day 63 after treatment under anaerobic conditions and remained constant until the end of the study. The half-live (DT_{50}) was calculated to 388 days based on first order kinetics.

No degradation product was detected in the course of the study. Two minor radioactive fractions remained unchanged during incubation (each one as max. 3.2%). Therefore these products were regarded as by-products, which were not formed in the soil, but originated from the application solution. The amount of non-extractable radioactive residues after extraction with hot water and acetonitrile increased from 4.8% on day 0 to 22% of the applied radioactivity on day 63 and then remained constant (21% at day 125). No radiolabelled CO_2 or other volatile compounds were detected.

Table B.8.1.2.b: Time course of the degradation of AE F039866 in sandy loam SLV, formation of metabolites (% of applied radioactivity

	Sampling Intervals [days]								
	0	1	5	7	13	29	63	95	125
Glufosinate	89	88	87	82	81	73	70	71	73
Z1+Z2	5.8	5.0	4.8	5.1	4.4	4.0	4.8	4.7	4.3
Total % extractable	94	93	92	87	85	77	75	76	77
^{14}C-CO_2	n.m.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Volatile organic	n.m.	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Non-extractable	4.8	4.4	7.1	10	12	18	22	21	21
Total %	99	97	99	97	97	95	97	97	98

n.m.. not measured

Comments

The study was well performed and reported. The results indicate that the degradation of GA in soil is much slower under anaerobic conditions. The calculated DT_{50} in the study is uncertain since 50% degradation was not reached at the end of incubation. Therefore, DT_{50} is set to >125 days. This should be taken into consideration in risk assessments at MS level.

Transmittal Document

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Studies Submitted:

Vol. 1 Degradation and Metabolism of Glufosinate Ammonium in Soil Under Anaerobic Conditions
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